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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/520,008

12/30/2004

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CAOI

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08/21/2006

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EXAMINER

MAKAR, KIMBERLY A

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10, drawn to a method of introducing a mutation into a target nucleic acid comprising a DNA having (1) an inverted repeat sequence and (2) a DNA sequence that is homologous to the target nucleic acid and subsequently transferring the DNA into a cell.

Group II, claim(s) 11-16, drawn to a kit for introducing a mutation into a target nucleic acid comprising (1) (a) a method of introducing a mutation into a target nucleic acid comprising a DNA having an inverted repeat sequence and (b) a DNA sequence that is homologous to the target nucleic acid and then transferring the DNA into a cell and (2) DNA having an inverted repeat sequence.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the invention lacks novelty. Hackett et al (US Patent No. 6,489,458) teaches a method of introducing mutations into a cell by using a member of the SB family of transposases (SB) and a nucleic acid fragment that includes a nucleic acid sequence with flanking inverted repeats (Column 10, lines 55-60). The instant specification teaches that the "target nucleic acid" is "any nucleic acid" (page 7, lines 7-8) and defines mutations as "a base substitution, deletion or insertion" (page 7, lines 16-18). Specifically, Hackett teaches that the DNA to be introduced into the cells is flanked by an inverted repeat sequences (column 13, line 66 through Column 14, line 10). He teaches that the nucleotide sequence to be introduced can contain insertional, loss-of-function or gain-of-function mutations (Column 32, lines 28-33).

3. The technical feature of Group I is a method of introducing a mutation into a target nucleic acid whereas the technical feature of Group II is a kit comprising a method of introducing a mutation into a target nucleic acid and DNA. The process of Group I is distinct from the composition of Group II. It is possible to utilize the method of Group I without the kit of Group II. Additionally, Group II comprises more than a methodology, but also contains DNA containing inverted repeat sequences, as well as

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potentially other enzymes, plasmid controls, buffers, protocols etc. These groups are biologically, functionally and compositionally distinct. Thus these groups are capable of supporting individual patents

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

5. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

6. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

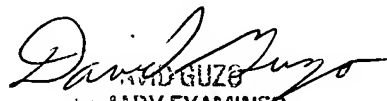
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Makar, Ph.D. whose telephone number is 571-272-4139. The examiner can normally be reached on 8AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KAM/07/12/06


DAVID GUZE
PRIMARY EXAMINER